REMARKS

Claims 1-14 were rejected. Claims 1-14 are pending.

Rejections Under 35 U.S.C. §102

The Examiner rejected Claims 1 and 2 for allegedly lacking novelty over Ragab (WO 00/57867, "the '867 patent"). Specifically, the Examiner asserted that the '867 patent teaches a sustained release temozolomide formulation comprising at least 3.3% temozolomide. Applicants respectfully traverse this rejection.

The '867 patent is directed to a method for treating a patient afflicted with cancer, comprising administering temozolomide to said patient for at least two cycles of a cyclical dosing schedule. In the '867 patent, several dosage forms of temozolomide, such as sustained release dosage form, are contemplated. However, the '867 patent neither provides any temozolomide sustained release formulation nor teaches how to obtain the sustained release formulation. Furthermore, although a content (3.3%) of temozolomide could be calculated from the description of the '867 patent (*see* page 4 of the '867 patent), the content is directed to a preferred temozolomide capsule formulation in the '867 patent, which is different from the controlled release system of claim 1. (In the '867 patent, sustained release dosage form is mentioned as a form of administration of temozolomide other than capsule formulation (page 4, lines 9-10 of the '867 patent)). It can be seen that the claimed system is actually not disclosed by the '867 patent. Thus claim 1 is not disclosed by the '867 patent and possesses novelty over the '867 patent. The dependent claim 2 also possesses novelty for the same reasons.

Rejections Under 35 U.S.C. §103

The Examiner objects to Claims 1-9 for being allegedly obvious in view of the combination of the '867 patent and U.S. Patent 6,086,908 ("the '908 patent"). Applicants respectfully traverse this rejection.

In the cited references, temozolomide has been found to be very rapidly absorbed in patients, reaching a maximum plasma concentration within 0.7 hours and having a half life of 1.8 hours. From these data, it can be seen that the plasma concentration of temozolomide declines rapidly after administration of the drug. Therefore, repeated administrations of the drug are required to maintain an effective concentration of the drug in the blood of a patient, which causes both inconvenience and discomfort to a patient receiving temozolomide. (*See* page 1, lines 19-30 of the specification.)

In order to address the problems associated with temozolomide administration, the claims recite a controlled release system for temozolomide which comprises a defined content of temozolomide (3% to 10% by weight) and a biodegradable polymeric material. The system can achieve controlled release of temozolomide, for example, for a 10-day period (*see* pages 12, lines 28-29 of the specification). The claimed system obviates the inconvenience of repeated administration of temozolomide and alleviates the sufferings of the patient.

However, there is no suggestion in the '867 patent and the '908 patent that a temozolomide controlled release system is obtained and the effects of controlled release are achieved. In contrast, the '867 patent teaches that temozolomide is administered daily (*see* page 1 line 33 of the '867 patent). In the '908 patent, only biodegradable polymeric materials are mentioned. It can be seen that even the combination of the '867 and '908 patents do not give any suggestion of obtaining a temozolomide controlled release system with the effects similar to the present invention.

Furthermore, it is known in the art that the poor absorbability of temozolomide limits its use and the control release of temozolomide is desired all along. There does not exist even one controlled release dosage form for temozolomide in the art until the present invention is provided.

Thus the technical solution of Claim 1 cannot be rendered obvious by the combination of the '867 and '908 patents. Thus dependent Claims 2-6 are also unobvious.

Claim 7 recites a process of preparing the temozolomide controlled release tablets. For the similar reasons as indicated above, Claim 7 and its dependent Claims 8-9 are also unobvious in view of the combination of the '867 and '908 patents.

The Examiner also rejected to Claims 7 and 10-14 for being allegedly obvious in view of the combination of the '867 patent, the '908 patent, and U.S. Patent 6, 753,014 ("the '014 patent").

The '014 patent discloses a process for preparing a microparticle; nevertheless, there is no teaching or suggestion for forming a temozolomide controlled release implantable tablet from the microparticle in the '014 patent. For the similar reasons, Claims 7 and 10-14 are also unobvious in view of the '867, '908, and '014 patents.

CONCLUSION

No fee is believed due. However, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayments, to Deposit Account No. 14-0629.

Respectfully submitted,
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/Christopher L. Curfman/ — January 6, 2009
Christopher L. Curfman — Date